

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JODI ROUVIERE and)	
ANDRE ROUVIERE,)	
)	
Plaintiffs,)	
)	
v.)	Case No. 1:18-cv-04814-LJL-SDA
)	
DEPUY ORTHOPAEDICS, INC. n/k/a)	
MEDICAL DEVICE BUSINESS)	
SERVICES, INC. and HOWMEDICA)	
OSTEONICS CORPORATION)	
d/b/a STRYKER ORTHOPAEDICS,)	
)	
Defendants.)	

DECLARATION OF DR. JOHN D. JARRELL PhD, PE

I, John D. Jarrell, PhD, PE hereby affirm and declare under penalties of perjury that the below facts and claims are true and correct:

1. I am over the age of 18 and a citizen of the United States. I currently reside in Rhode Island.
2. I am qualified to render opinions as a result of my education and training in materials science and engineering, medical science, biology and mechanical engineering, as well as my own research and testing. I am an experienced doctor of medical science and multi-discipline engineer specializing in the analysis of complex designs, accidents and failures involving materials, mechanical and biological systems. I have been a licensed Professional Mechanical Engineer since 1996 and actively involved in engineering analysis, design, product development and research. I have earned three degrees from Brown University, a Bachelors and Masters of Science in Materials Science and Engineering and a Doctorate in Biology, Medical

Science and Engineering and received medical training in histology, physiology, microbiology and pathology. I have received an appointment at the Alpert Medical School of Brown University and at Rhode Island Hospital as teaching associate in the Department of Orthopaedics. I have over 29 years of experience with the evaluation of minimally invasive devices and powered cutting devices, medical devices, instruments and medical implants. I have attached hereto my curriculum vitae as Exhibit A.

3. On or about October 28, 2020, I was retained by the law office of Law Offices of Andre A. Rouviere to evaluate the explanted hip prosthesis systems manufactured by DePuy Orthopedics and Stryker Orthopedics and review documentation and data to determine if the components were defective in either their manufacture, design and/ or failure to adequately warn related to the above referenced matter.

4. On November 9, 2020, I submitted my written report and opinion after evaluating the available evidence, materials and documentation related to explanted hip prosthesis systems manufactured by DePuy Orthopedics and Stryker Orthopedics. I have attached my report and opinion hereto and marked Exhibit B.

5. On or about March 22, 2021, I received in its entirety the report and opinion of Dr. Gannon dated March 22, 2021, wherein I learned for a first time the results of the examination of tissue specimens of Jodi Rouviere labeled/marked S16-15059, S17-2298 A1, and S17-2298 B1. See Exhibit C hereto. Dr. Gannon opined or otherwise concluded the following in his report:

a. “The slide labeled S16-15059 shows densely collagenized fibrous and fibroadipose tissue with abundant metal-laden macrophages (Fig 1 below).”

b. “The slide labeled S17-2298 A1 consists of densely collagenized fibrous and fibrovascular tissue with numerous metal-laden macrophages, tissue necrosis, larger metal particles consistent with titanium debris and lymphocytes (Fig 2 below). Additionally, granulomas are seen indicating a type 4 hypersensitivity reaction. The larger titanium particles were not a feature of the tissue available in my original report.”

c. “Slide S17-2298 B1 shows bone and bone marrow (Fig 4 below). The bone is severely osteopenic with numerous resorptive surfaces and remodeling. The bone marrow shows trilineage maturation with no atypical features in this material.”

Id., at pp.____.

6. Dr. Gannon further opined that “[t]aken together, these slides show an ongoing and severe adverse reaction to metal debris in Mrs. Rouviere that continues despite revision in her prosthesis. These changes will likely continue as the metal has been shown in this material to stay resident in the body leading to additional pain and suffering.” *Id.*, at p.____.

7. Dr. Gannon further opined that “had [he] the chance to review these slides several of his answers in his previous deposition would have been modified to include, but not limited to, ongoing immunologic responses and tissue damage in Mrs. Rouviere as a result of retained metal particles and the lack of correlation between serum ion levels and the ongoing tissue destruction.”

8. Dr. Gannon further concluded:

“Substantial amounts of wear debris from the Cobalt and Chromium (CoCr) from metal hip implants were released into the joint tissue environment of the synovium and surrounding capsule. This wear debris was ingested by macrophages that were present and were recruited to the local environment. The metal wear debris ingestion leads to localized cellular death and significant scarring. This necrosis is directly associated with the metal laden macrophages. These morphologic and

physiologic changes led to clinical symptoms and/or findings in this case, which necessitated right hip revision surgery. Mrs. Rouviere experienced an adverse reaction to metal debris as a result of wear from metal-to-metal contact in the implanted hip components. This led to accumulation of metal wear debris in and around the implant site, causing subsequent tissue destruction, bone damage, pain and difficulty ambulating and eventually leading revision surgery.”

Id., pp.____.

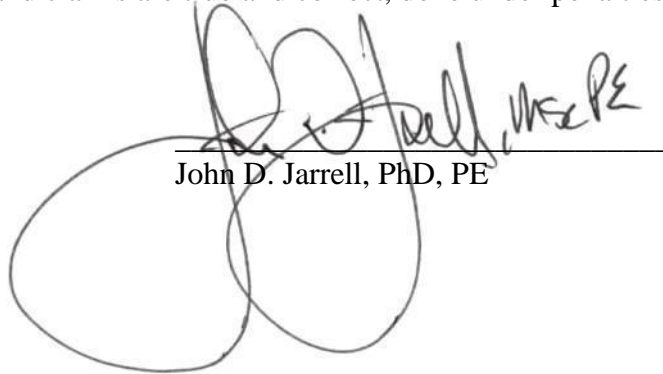
9. Had I been provided the information contained in Dr. Gannon’s report described in the preceding paragraphs of this declaration, which included Dr. Gannon’s identification of titanium, I would have been able to correlate titanium wear from the stem with the finding of titanium in the tissue with a definitive degree of certainty. I would have included that in my report and opinion dated November 9, 2021 and used it to confirm my findings that there was a significant amount of titanium disbursed into Mrs. Rouviere’s body.

10. It is important to note that prior to the examination by Gannon of the news slides, there was no identifiable designation between the metals found in the Plaintiff’s tissues and the medical devices or hip components of Defendant DePuy. However, with these newly disclosed tissue specimen slides showed the presence of titanium debris. This is new and concrete evidence that DePuy devices were the contributor of the metal into Mrs. Rouviere’s body.

11. Based on the newly produced tissue specimens labeled S16-15059, S17-2298 A1, and S17-2298 B1, and Dr. Gannon’s Report and Opinion dated November 9, 2021, my original report and opinion dated November 9, 2021, is now rendered incomplete, altered and need of modification for the reasons stated in the preceding paragraphs of this declaration.

AFFIDANT SAYEHT NOT

PURSUANT TO TITLE 28 U.S.C. 1746, I, John D. Jarrell, PhD, PE hereby declare and affirm that the foregoing facts and claims are true and correct, done under penalties of perjury on this 25th day of March 2021.



John D. Jarrell, PhD, PE

